JUL 25 2012

510(k) Summary

I. Administrative

Submitter of the Application:

Trigen Laboratories
2400 Main Street
Suite 6
Sayreville, NY 08872
Phone: 732-721-0070
Fax: 732-721-3430

Contact Person: Pamela Chiappone

Date of Preparation: March 20, 2012

II. Device Name:

Proprietary Name:	TL Triseb Cream
Common Name:	Dressing, Wound and Burn, Hydrogel w/Drug and /or Biologic
Product Code:	FRO
Device:	Unclassified

III. Substantial Equivalent Device:

Trigen Laboratories Inc. believes that TL Triseb Cream is substantially equivalent to the currently marketed device, Promiseb® Topical Cream cleared under K050158.

IV. Device Description:

TL Triseb cream is a non-sterile viscous emulsion/cream formulation. TL Triseb Cream is an off-white, steroid-free, fragrance-free, water-based emulsion.

V. Intended Use:

The prescription product requires a physician to diagnose the disease state.

VI. Summary of the Technological Characteristics of the Device Compared to the Predicate Device(s):

All Products referenced are non-sterile emulsions that are applied topically to relieve the signs and symptoms of seborrhea and seborrheic dermatitis.

Table 1, below, provides a technological comparison of TL Triseb and the predicate device.

Table 1. Technological Comparison

Product Name	TL Triseb Cream	Promiseb® Topical Cream
510(k)		**K050158**
Ingredients	Purified water, isohexadecane, butyrospermum parkii, pentylene glycol, ethylhexyl palmitate, cera alba, PEG-30 dipolyhydroxystearate, bisabolol, polyglyceryl-6 polyricinoleate, tocopheryl acetate, hydrogenated castor oil, butylene glycol, magnesium sulfate, piroctone olamine, allantoin, magnesium stearate, disodium EDTA, ascorbyl tetraisopalmitate, and propyl gallate.	Purified water, isohexadecane, butyrospermum parkii, pentylene glycol, ethylhexyl palmitate, cera alba, PEG-30 dipolyhydroxystearate, bisabolol, polyglyceryl-6 polyricinoleate, tocopheryl acetate, hydrogenated castor oil, acifructol complex, butylene glycol, magnesium sulfate, piroctone olamine, allantoin, magnesium stearate, disodium EDTA, vitis vinifera, ascorbyl tetraisopalmitate, glycyrrhetinic acid, propyl gallate, and telmesteine.
# Applications Per day	2 to 3 times per day or as needed	2 to 3 times per day or as needed
Indications for Use	Under the supervision of a healthcare professional, TL Triseb Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. TL Triseb Cream helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.	Under the supervision of a healthcare professional, Promiseb Topical Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. Promiseb Topical Cream helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.
Product Description	TL Triseb Cream is an off-white, steroid-free, fragrance-free, water-based emulsion.	Promiseb Topical Cream is an off-white, steroid-free, fragrance-free, water-based emulsion.
Physical Properties	Non-sterile, white cream Viscosity 205,920 cps Consistency: smooth homogeneous Microscopy: Uniform emulsion	Non-sterile, white cream Viscosity 228,800 cps Consistency: smooth homogeneous Microscopy: Uniform emulsion

Clinical Performance Data

Repeat Insult Patch Testing with 50 human subjects showed TL Triseb Cream to be a non-primary irritant and non-primary sensitizer to the skin.

Nonclinical Performance Data:

In a L929 Agar Overlay Cytotoxicity study using TL Triseb Cream, the cells exhibited a slight reaction, meeting the requirements of the L929 Agar Overlay Cytotoxicity Test as described in ISO 10993-5 and USP 23, Biological Reactive Tests *In-Vitro* (87).

VII. Conclusion

Functional and performance testing has been conducted to assess the safety and efficacy of TL Triseb Cream and the results are satisfactory. Based on the information provided herein, we conclude that the device is substantially equivalent to the predicate, Promiseb Topical Cream.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 25 2012

Trigen Laboratories, Incorporated
% Pharmaceutical Project Solutions, Incorporated
Ms. Melissa Goodhead
11705 Boyette Road, Suite 171
Riverview, Florida 33569

Re: K121134
Trade/Device Name: TL Triseb Cream
Regulatory Class: Unclassified Dressing
Product Code: FRO
Dated: June 20, 2011
Received: June 22, 2011

Dear Ms. Goodhead:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121134

Device Name: TL Triseb Cream

Indications for Use:

Under the supervision of a healthcare professional, TL Triseb Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. TL Triseb Cream helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Prescription Use: X AND/OR Over-the-Counter Use: _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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